

## **REMARKS/ARGUMENTS**

Claims 1 and 7-14 are pending. Claims 48 and 49 have been canceled. Claim 1 has been amended. The claim amendments are supported by the specification as filed and suggested by the Examiner. Non-limiting supporting disclosure can be found at page 6 lines 27 to line 5 of page 7, Example 5, Figure 5, and at page 12 line 32 to at page 13 line 17. Claims 2-6 and 15-47 were previously cancelled. Upon entry of this response, claims 1 and 7-9 are under examination. No new matter is introduced by this Response, and thus entry thereof is respectfully requested.

As a preliminary matter, Applicant thanks the Examiner for the helpfulness of the Office Action and appreciates the suggestions provided by the Examiner. Applicant also thanks the Examiner for the withdrawal of the rejections under 35 U.S.C. §102(e).

### **I. Rejoinder**

Previously, the Examiner required restriction between six groups of claims. Applicant provisionally elected Group I (claims 1-6, 8-9 and 15-22) and traversed on the grounds that Group I, Group II (claims 1-6, 10-12 and 15-22) and Group III (claims 1-6 and 13-22) are classified in the same class and subclass. Furthermore, Applicant pointed to claim 7 as a generic claim which links Groups I, II and III. Group I has been under examination thus far. Upon entry of this response, if claim 7 is found allowable, Applicant respectfully requests rejoinder of withdrawn claims 10-14 from Groups II and III. These claims require use of the method of claim 7 and include at least the limitations thereof.

### **II. Claim Rejection under 35 U.S.C. §112**

#### **A. Enablement**

The Examiner rejected claims 1, 48 and 49 under 35 U.S.C. §112, first paragraph “[t]o the extent that [the claims] broadly embrace an in vivo method of treating a human subject suffering from rheumatoid arthritis or allergy comprising contacting the T cell with an agent that inhibits

rheumatoid arthritis (RA) or allergy...” for allegedly lacking enablement. Office Action, pp. 3-4. However, the Examiner acknowledges that the specification is enabling for

“A method for inhibiting T cell activation in a subject wherein the subject suffers from rheumatoid arthritis or allergy comprising contacting T cells with an agent which inhibits phosphatidylinositol 3-kinase in the T-cells, wherein the agent is not a wortmannin, wherein the agent inhibits IL-2 production in vitro when said agent is applied to T cells that are stimulated by B-7-1 or B7-2, thereby inhibiting T cell activation in the subject suffering from rheumatoid arthritis or allergy.”

Office Action, p. 4.

Applicant respectfully traverses the rejection. Claim 1 recites that the subject suffers from one or more defined diseases, namely rheumatoid arthritis or allergy. Applicant respectfully submits that one of skill would know how to treat rheumatoid arthritis or allergy when provided with the explicit teaching that inhibiting phosphatidylinositol 3-kinase in the T-cells can down-regulate T cell activation without undue experimentation.

Nevertheless, and solely in order to expedite prosecution, claim 1 has been amended to recite the above enabled aspect suggested by the Examiner. Accordingly, the rejection is moot.

#### **B. New Matter**

The Examiner rejected claim 49 under 35 U.S.C. §112, first paragraph for allegedly containing “subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Office Action, pp. 10. The Examiner states that it “is not clear that the Applicant was in possession of a genus of undefined of ‘IL-2 production ... when less than about 100 nM of said agent is applied to T cells’ including any open ended numerical range at the time the application was filed.” Id.

Applicant respectfully traverses the rejection. Claims without reciting an upper or lower limit are not indefinite *per se*. The original specification clearly defines the metes and bounds of the dosage. However, and solely in order to expedite prosecution, a range of “about 1 nM to about 100

nM of said agent” is introduced into claim 1, which now incorporates the limitation of claim 49. Support for the amendment is found in, for example, Example 5 and Figure 7B of the application as filed. Accordingly, the rejection to claim 49 is moot. Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. §112, first paragraph.

#### **IV. Claim Rejection under 35 U.S.C. §103**

The Examiner rejected claim 1 but not claim 49 under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent 5,504,103 (hereinafter “Bonjouklian”) in view of Vitali et al., Int J Artif Organs. 1993 Dec;16 Suppl 5:196-200 (hereinafter “Vitali”) or Bochner et al., 1994 Ann Rev Immunology, pp. 295-335.

Applicant respectfully traverses the rejection because the cited references (Bonjouklian, Vitali, and Bochner) alone or in combination do not teach or even hint at the following claimed aspect: “wherein the agent inhibits IL-2 production *in vitro* when said agent is applied to T cells that are stimulated by B7-1 or B7-2.” Indeed, the Examiner has acknowledged that the primary reference by Bonjouklian “does not disclose in vitro inhibition of IL-2 in T cell expressing a CD28 cell surface receptor and simulated by its natural ligands B7-1(CD80) and B7-2(B70).” See Action at page 7.

However, in a sincere effort to place this application in condition of allowance but without acquiescence to the Examiner’s rejection, Applicant has amended claim 1 to incorporate the limitation of claim 49. As is acknowledged by the Examiner, claim 49 is not obvious in view of the cited art, neither is claim 1 that has now incorporated the limitation of claim 49. Thus this rejection is rendered moot.

#### **V. Obvious Type Double Patenting**

The Examiner rejected claims 1, 7-9 and 48 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7-10 of U.S. Patent No. 6,632,789. Office Action, p. 5.

Claim 48 is canceled, rendering the rejection to claim 48 moot.

The rejection of claims 1 and 7-9 are moot in view of the Terminal Disclaimer submitted herewith. Notwithstanding the Terminal Disclaimer, Applicant respectfully notes that claims 1-4 and 7-10 of U.S. Patent No. 6,632,789 contain patentably distinct elements that are not present in claims 1 and 7-9 of the instant application, and vice-versa.

**CONCLUSION**

Applicant submits that this paper fully addresses the Office Action mailed April 13, 2010. An issuance of Notice of Allowance is earnestly requested. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned attorney at (650) 849-3383. The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 35280-730.401).

Respectfully submitted,



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By: \_\_\_\_\_

Tao Huang, Ph.D., J.D. (Reg. No. 60,008)

Karen K. Wong, Ph.D., J.D. (Reg. No. 44,409)

WILSON SONSINI GOODRICH & ROSATI  
650 Page Mill Road  
Palo Alto, CA 94304  
(650) 849-3383  
Customer No. 021971